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REMARKS

Favorable reconsideration of this application is requested. The limitation in claim 1 of treating mammals suffering from a renal disorder that is a chronic recurrent urinary tract infection is supported by original claim 2. The recitation of "complicated or uncomplicated" in claim 1 is supported at page 4, line 28. Claims 3, 4, 7 and 8 are amended editorially. Claim 15 is written in independent form and also tracks the revisions to claim 1. Claims 2, 5, 6 and 9-13 have been cancelled without prejudice to or disclaimer of the subject matter involved.

Rejection of claims 1-4 and 12 under 35 U.S.C. § 102 (b):

Claims 1-4 and 12 have been rejected as anticipated by De Souza et al. (US 2002/0142055). The rejection contends that De Souza et al. teaches standardization of an extract of *Tinospora cordifolia* and use of such a standardized extract for the administration of mammals, and further that De Souza et al. teaches that the extract is administered with a conventional therapy. The rejection contended that claim 1 as originally presented required that the extract be administered to "mammal", but that the mammal was does not required to have a renal disorder. Favorable reconsideration of this rejection is requested.

Claim 1 requires the treatment of a mammal who is in need of treatment for a renal disorder, particularly, chronic recurrent urinary tract infection. Since De Souza et al. (US 2002/0142055) does not teach, either expressly or inherently, use of standardised extract of *Tinipora cordifolia* for the treatment of a mammal suffering from a renal disorder, particularly chronic recurrent urinary tract infection, Applicant respectfully submits that it does not anticipate claim 1 as well as claims 3 – 4 which are dependent therefrom.

Page 3 of the Office Action refers to Example 5 of De Souza et al. In fact, Example 5 is specifically directed to use of the standardized extract as adjuvant therapy in patients with osteomyclitis. Moreover, specification of De Souza et al. (US 2002/0142055) repeatedly makes specific reference to osteomyelitis, cancer, diabetes and respiratory system disorders as the diseases related to immunity. See paragraphs [0022], [0023], [0024], [0025], [0033], [0034], [0035], [0036] and [0037] and also the examples of US 2002/0142055.

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Therefore, claim 1 and its dependents are not anticipated by De Souza et al. (US 2002/0142055) and the rejection should be withdrawn. Applicants are not conceding the correctness of the rejection for the canceled claims or any dependent claims not separately argued.

Rejection of claims 1-4, 7, 8, 12, 13 and 15 under 35 U.S.C. § 103 (a):

Combination of De Souza et al (US 2002/0142055) and Upadhyay et al. (US 6,251,383):

Claims 1-4, 7, 8, 12, 13 and 15 are rejected as obvious in view of the combination of De Souza et al. (US 2002/0142055) and Upadhyay et al. (US 6,251,383). Applicants respectfully traverse this rejection.

Page 5 of the Office Action specifically referred to a portion (column 2 , lines 29 –32 under the heading “background of the invention”) of the Upadhyay patent reading: “Plants of the *Tinospora* species have been widely used in traditional Indian medicine for treatment of skin infections, arthritis, fever, dysentery, urinary tract infections, and diabetes”. The rejection relies on this as evidence that one of ordinary skill in the art would have contemplated *Tinipora cordifolia* as one of the species in the *Tinospora* genus to be used for the treatment of urinary tract infections and that it clearly would have been within the purview of the ordinary artisan to use the extract for chronic recurrent urinary tract infections since the extract is already noted to be used for urinary tract infections. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Upadhyay is specifically directed to a method for ex vivo expansion of the number of hematopoietic cells for various clinical applications like transplantation of ex vivo expanded hemopoietic cells for restoration of immunocompetence, generation of activated and antigen sensitized immunocompetent cells for immunotherapy of cancer and infections, and ex vivo expansion of genetically transfected or transformed hematopoietic cells for gene therapy. The

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background section of Upadhyay merely mentions that plants of the *Tinospora* species have been widely used in traditional Indian medicine for treatment of skin infections, arthritis, fever, dysentery, urinary tract infections, and diabetes. Thus, Upadhyay makes reference to *Tinospora* species in general and urinary tract infections are mentioned as one of several diseases in the treatment of which plants of *Tinospora* species had been used. There is no teaching that the plant *Tinospora cordifolia* could be used in the treatment of urinary tract infections, and there is no reasonable basis to interpret this to indicate that all *Tinospora* species were considered useful for all of the indicated conditions. As noted above, De Souza et al. (US 2002/0142055) teaches the use of the standardized extract of *Tinospora cordifolia* as an adjuvant therapy in patients with osteomyelitis, cancer, diabetes and respiratory system disorders.

On the other hand, claims 1 and 15 are directed to a method for the treatment of a mammal who is suffering from a renal disorder, particularly, chronic recurrent urinary tract infection. As noted above, Upadhyay cannot be considered to teach that *Tinipora cordifolia* is used to treat urinary tract infections, much less urinary tract infections that are "chronic and recurrent" as required by claims 1 and 15, or that another agent is used along with the extract as required by claim 1. Therefore, the invention of claims 1 and 15 and their dependents is not obvious over Upadhyay and De Souza taken alone or in combination.

Combination of De Souza et al. (US 2002/0142055) and Upadhyay et al. (US 6,251,383) with Solanki (US 2003/0147896)

Claims 1-4, 7, 8, 12, 13 and 15 are rejected as obvious in view of De Souza et al. (US 2002/0142055) and Upadhyay et al. (US 6,251,383), further in view of Solanki (2003/0147896). This rejection is respectfully traversed.

De Souza et al and Upadhyay have been discussed above. The rejection relies on Solanki as teaching the use of *Tinospora cordifolia* to treat a patient who has renal failure and that using the extract helped the kidneys in filtering excess protein and calcium. Page 7 of the Office Action refers to paragraphs 3, 24 and 25 of Solanki (2003/0147896). Applicants respectfully suggest that the rejection misapprehends Solanki, and that Solanki does not remedy the deficiencies of De Souza and Upadhyay.

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In paragraph 3 of the specification, Solanki specifically indicates that the invention is related to a polyherbal composition comprising a mixture of the following seven herbs: *Tinospora cordifolia*, *Chlorophytum borivilianum*, *Curcuma longa*, *Asparagus racemosus*, *Hygrophila auriculata*, *Achyranthus aspera* and *Elephantopus scaber*, or a mixture of the active ingredients that have been extracted from those herbs or chemically synthesized. Moreover, paragraph 5 of Solanki specifically states that "an important feature of the product of the present invention is that it contains a mixture of herbs, or extracts from herbs, rather than being based on a single herb. A synergistic effect has been noticed between the various ingredients." Thus, Solanki fails to provide an expectation that any one of the indicated herbs would have any particular activity or benefit.

Also, Solanki is directed to use of the polyherbal composition for the treatment of cancer or as an adjuvant to conventional modes of anticancer therapy, namely radiotherapy and/or chemotherapy. In paragraphs 24 and 25, Solanki has demonstrated the advantages of the use of polyherbal composition in the treatment of a 92 year old patient having multiple myeloma with renal failure in terms of reduction in serum creatinine and urea. However, the use as indicated in the specific paragraphs is exclusively directed to use in a patient having multiple myeloma and it was not intended to treat renal failure in the patient. In view of this and taking into consideration the fact that Solanki expressly teaches away from use of a single herb such as *Tinospora cordifolia*, a person of ordinary skill in the art would not be motivated to use a standardised or even a non-standardised extract of *Tinospora cordifolia* for the treatment of a renal disorder, particularly, chronic recurrent urinary tract infection in a mammal who is in need of such treatment. Again, the only suggestion or incentive provided by Solanki concerns the advantages of using polyherbal composition containing *Tinospora cordifolia* along with six other herbs for the treatment of cancer or as an adjuvant therapy in the treatment of cancer, particularly myeloma, but not the use of a standardised or even a non-standardised extract of *Tinospora cordifolia* for the treatment of a renal disorder, particularly, chronic recurrent urinary tract infection in a mammal who is in need of such treatment. Therefore this rejection also should be withdrawn.

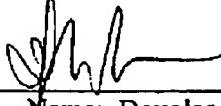
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In view of the aforementioned amendments and remarks, Applicants respectfully contend that the rejections of the claims under 35 U.S.C. §§ 102 (b) and 103 (a) are overcome. Accordingly, favorable reconsideration in the form of a Notice of Allowance is requested.

Respectfully submitted,

HAMRE, SCHUMANN,
MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
Phone: 612-455-3800

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By 

Name: Douglas P. Mueller
Reg. No. 30,300
Customer No. 52835